

Remarks

Claims 1, 13 and 31 are amended herewith. Claims 33 and 34 are newly submitted. Claim 2 is hereby cancelled. Claims 3, 7, 12, 16, 17 were previously cancelled. Claims 25-29 were withdrawn as a result of an earlier restriction requirement. Claims 1, 8-11, 13-15, 18-24, 30-31 and 33-34 are pending in the application.

Substance of the Interview

A telephone interview was conducted between Examiner Amanda Marie Shaw, her supervisor Juliet Switzer, Dr. Chantal Guillemette, sole inventor on the present patent application and patent agent Louise G. Bernier, on April 8, 2008.

Possible amendments to claim 1 were discussed to overcome objections of scope of the claims:

- 1) The discussion involved possible amendment so as to recite "A method for detecting polymorphism" or "A method for screening individuals for variation in glucuronidation."
- 2) Further discussion involved the fact that additional data has been generated since the filing of the patent application supporting the original data in addition to providing better statistical significance. The Examiner requested that this data be provided by way of declaration.

No agreement has been reached between the agent of the applicant and the Examiner as a result of this telephone interview, but amendments were brought to the claims as well as newly submitted claims 33 and 34 to address point 1. In addition, a declaration is provided herewith to support additional data validating the data presented in the original patent application to address point 2 as discussed.

Applicant wishes to thank the Examiners for helpful discussion and suggestions.

Amended claims

In the present amendment, claim 1 has been amended so as to recite “...screening human individuals for variations in UGT1A9 metabolism of...” instead of “...determining the predisposition or susceptibility of a human individual to an adverse reaction, a side effect or a variation in response to therapy to a biologically active...”. This amendment to claim 1 finds support in the application as filed at page 9, line 1: “*glucuronidation metabolism*”, page 12, line 16: “*glucuronidation kinetic parameters*” as well as Example II presenting identification of human subject bearing UGT1A9 variants. As well, claim 1 now recites “increased UGT1A9 glucuronidation activity of said compound” instead of “said predisposition or susceptibility”. This amendment to claim 1 finds support in the application as filed at Figure 12.

As well, newly submitted claims 33 and 34 find support in the application as filed, and particularly on page 9, line 1, page 12, line 16 and Figure 12.

Claim objections

On page 2 of the office action, the Examiner has objected to claim 1 because of an informality. Please note that the amendments brought to claim 1 obviates this objection.

Claim rejections under 35 U.S.C. § 112

On page 3 of the office action, the Examiner has rejected all claims on the basis of 35 U.S.C. § 112, first paragraph, as presumably failing to comply with the enablement requirement. More precisely, the Examiner has objected to the scope of the claims because of the expressions “adverse reaction” and “side effect or a variation in response to therapy”. In order to overcome this rejection, and strictly to advance prosecution in this application, applicant has amended claim 1 to read “a method for screening human individuals for variations in UGT1A9 metabolism”. It is argued that this amendment brought to claim 1 brings the scope of the claim commensurate with the data that is provided in the application as filed and overcomes this rejection.

In addition, still with respect to the scope of the claims, the Examiner contends that the claims are too broad because it is unknown whether the presence of the T-275A substitution has to be present in a homozygous or heterozygous state. Applicant submits that the results presented in the application all point to the fact that a single substitution in a heterozygote human subject is sufficient to present a statistically significant increase in the glucuronidation activity of the UGT1A9 gene. Furthermore, the studies presented by the Applicant as well as follow-up studies carried out by Applicant and other groups have, up until now, never identified a homozygote individual bearing two copies of this substitution in the promoter of the UGT1A9 gene. It can therefore be predicted with a high level of certainty that either: a) these individuals are non-viable, therefore will not be found in the population, or b) such individuals are extremely rare and will have *at the very least* the same increase in glucuronidation activity as in their heterozygote counterparts. Therefore, Applicant does not believe that providing additional data with respect to homozygote individuals is appropriate or necessary at this time to support the claims. Withdrawal of this rejection is respectfully requested.

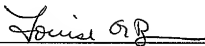
On page 5 of the office action, the Examiner further states that the claims are rejected for enablement on the basis that the data provided in the specification provides a $\text{Prob} > F$ value greater than 0.05 ($\text{Prob} > F$ 0.0611 in Figure 12), which suggests that these findings are not considered statistically significant. In the attached Declaration, Applicant presents additional data that have been generated by the present applicant as well as other independent groups after the filing of the present application to support the data generated in the current patent application. Such additional data provides probability values that are much lower than 0.05 (see Declaration paragraph 8 where P can be as low as 0.006; and paragraph 9 where P is as low as 0.009). Indeed, the declaration by Dr. Chantal Guillemette which is enclosed herewith provides several instances taken from three (3) different peer reviewed scientific papers emanating from three (3) different research groups indicating that the T-275A substitution of the UGT1A9 promoter is indeed significant and reproducible. The Examiner is therefore requested to withdraw based on 35 U.S.C. § 112, first paragraph.

In view of the above, allowance of claims 1, 8-11, 13-15, 18-24, 30-31, 33 and 34 on the merits and at an early date is therefore respectfully requested.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

No fees are believed to be required by the present response. However, should this be an error, authorization is hereby given to charge deposit account 19-5113 for any underpayment or to credit any overpayment.

Respectfully submitted,



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Enclosures: Declaration of Chantal Guillemette and CV
IDS
5 references